UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

Tommy Mitchell Taylor,	)	Civil Action No.: 3:15-2091-MBS
	)	
Plaintiff,	)	
	)	
v.	)	**COMPLAINT**
	)	(Jury Trial Demanded)
CVRx, Inc.,	)	
	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff, Tommy Taylor, by and through his undersigned counsel, complaining of the above-named Defendant, and for cause of action, alleges and states as follows:

BACKGROUND & NATURE OF THE ACTION

1. In 2008, Plaintiff was diagnosed with malignant hypertension, a condition that causes dangerously high blood pressure. Soon thereafter, Plaintiff began seeking treatment from medical providers throughout the United States for a solution to the malady. Unfortunately, medical providers were unable to successfully treat Plaintiff's malignant hypertension. After conducting his own research, Plaintiff discovered an online article about a study being sponsored by Defendant CVRx, Inc. for a medical device that can successfully regulate high blood pressure. Defendant was seeking participants for a trial of the device in the United States and provided a telephone number on its website that interested applicants could call. After leaving his information by voicemail, Plaintiff was contacted the same day by a representative of Defendant CVRX, Inc. and provided additional information regarding his medical condition. Plaintiff was later contacted by a physician working for Defendant CVRx, Inc. to further discuss his medical condition and past treatment.

2. In 2009, Plaintiff agreed to participate in a clinical trial sponsored by Defendant in which a study device called the CVRx® Rheos® Baroflex Hypertension Therapy™ System (Rheos System) would be implanted inside Plaintiff. According to Defendant's Consent Form, the Rheos System is an investigational device that is designed to lower blood pressure by stimulating the body's natural blood pressure regulators which are located in the carotid arteries. The Rheos System has 3 parts: a battery powered pack that is surgically placed under the skin near the patient's collarbone and 2 wires (leads) that go under the skin from the battery powered pack to the left and right arteries of the neck.

3. Plaintiff agreed to participate in the study and Defendant arranged for the Rheos System to be implanted within Plaintiff in 2009. As part of the trial, Defendant required that Plaintiff follow up with his assigned study doctor for periodic monitoring after the initial procedure. Plaintiff was advised that the battery in the Rheos System should last between 1 to 2 years.

4. Following the initial procedure, Plaintiff was compliant with Defendant's instructions concerning follow up visits for testing of the device and monitoring of Plaintiff's condition. Plaintiff was informed prior to the initial procedure that he would be followed by Defendant for four to five years. In 2014, Defendant informed Plaintiff that if he agreed to continue in the study that such participation may continue for up to five more years. Defendant informed Plaintiff in 2014 that the Rheos System was a permanent implant and that he would need to return to a clinic annually until the device became approved or five years from signing the informed consent in 2014, whichever came first. Plaintiff was informed in 2014 that the Rheos System may need to be replaced with a second generation device called the Barostim

Neo™ Legacy device. Defendant later replaced Plaintiff's Rheos System with the Barostim Neo™ Legacy device.

5. Plaintiff received assurances from Defendant's representatives prior to the initial surgery and numerous times thereafter that Defendant would continue to service the device at its own expense even if the Rheos System did not receive FDA approval. In 2014, Defendant informed Plaintiff that it would reimburse the medical center and/or doctors for their fair costs for the following tests and procedures required for the study:

a. Follow-up tests and procedures described above in this form and required only for the study.

b. Device removal if Plaintiff requested that the Rheos System be removed while he was in the study;

c. Battery replacement while Plaintiff was in the study if there is no FDA approved device available.

6. Defendant agreed that its representatives would provide technical expertise on the device, be present at follow up visits or device related surgery, assist in programming the device or running tests, have direct contact with Plaintiff, and be aware of how Plaintiff's device was programmed and test results.

7. In or about February of 2015, Dr. Stephen Motew, the principal investigator for the clinical trial, sent a letter to Plaintiff advising that Defendant was no longer seeking FDA approval for the Rheos System. Within this letter, Plaintiff was informed that the FDA had granted Defendant a Humanitarian Use Device Exemption for the device but that the study would close on April 03, 2015. Plaintiff was urged to contact a research coordinator to discuss a "transition plan."

8. After receiving the letter in February of 2015, Plaintiff contacted a representative of Defendant and was provided with three options: (1) Defendant would pay for the removal of the device through April 1, 2015; (2) Plaintiff could keep the device in his body, working until the battery died in less than one year; or (3) Plaintiff could replace the device at his own expense every twelve to fourteen months. Plaintiff was informed that it would cost over $400,000.00 each time the device needed to be replaced and that Medicare would not cover these costs. Plaintiff does not have the financial means to have the device replaced every 1 to 2 years. Plaintiff is informed that the battery on the device will likely expire between August and October of 2015.

9. Plaintiff brings this action for injuries and damages as a proximate result of Defendant's misrepresentations, fraud, deceptive marketing and promotion of the Rheos System, contractual violations, failures throughout the clinical trial, and negligence.

PARTIES

10. Plaintiff Tommy Mitchell Taylor is a resident and citizen of Lexington County, South Carolina.

11. Plaintiff claims and alleges that his damages and injuries are the direct and proximate result of Defendant's negligent, intentional, and wrongful acts, omissions, and conduct regarding Defendant's promotion, advertising, and marketing of the Rheos System as well as any violations, contractual or otherwise, that occurred during Plaintiff's participation in the clinical trial.

12. On information and belief, Defendant CVRx, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business located at 9201 W. Broadway, #650, Minneapolis, Minnesota 55445. On information

and belief, Defendant CVRx, Inc. is in the business of designing, researching, developing, marketing, researching, distributing, packaging, promoting, and selling medical devices across the United States, including within the State of South Carolina.

13. Upon information and belief, Defendant CVRx, Inc. regularly transacts business in the State of South Carolina.

JURISDICTION AND VENUE

14. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

15. This action is properly before the Court because there is complete diversity of citizenship between Plaintiff and Defendant and the amount in controversy claimed by Plaintiff exceeds $75,000. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. §1332(a). In addition, this is an action based on Defendant's violations of federal law, including relevant provisions of 21 CFR 812.

16. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this district.

17. Defendant CVRx, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Minnesota. Accordingly, for purposes of diversity jurisdiction, it is a citizen of Delaware and Minnesota.

18. On information and belief, Defendant regularly places goods into the stream of commerce for distribution in South Carolina and throughout the United States. Venue is proper within this District pursuant to 28 U.S.C. §1391. Defendants are subject to personal jurisdiction within this District in accordance with 28 U.S.C. §1391(c), in that Defendants did and do business within and have continuous and systematic contacts with the state of South Carolina,

have consented to jurisdiction in the state of South Carolina and/or committed a tort in whole or in part in the state of South Carolina against Plaintiff, as more fully set forth herein. On information and belief, defendants also advertised in this district, and made material omissions and representations in this district.

THE CAUSES OF ACTION

COUNT I

NEGLIGENCE & GROSS NEGLIGENCE

19. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

20. Defendant, directly or indirectly, caused the Rheos System to be distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. Defendant further solicited Plaintiff's participation in the clinical trial for the Rheos System.

21. Defendant had a duty to exercise reasonable care throughout the clinical trial in the research, testing, marketing, advertisement, compliance and promotion of the Rheos System, including refraining from making false representations to Plaintiff that it would continue to service and maintain the device at its own expense regardless of FDA approval. Defendant also had a duty to exercise reasonable care throughout the clinical trial by complying with FDA regulations, good clinical practices, the investigational plan, reporting requirements, guidelines, monitoring, recording requirements, and FDA procedures.

22. During the time that Defendant promoted, marketed, advertised, or made representations about the device to Plaintiff, it failed to accurately and reasonably inform Plaintiff that he would be responsible for any expenses to maintain the device if FDA approval was not granted.

23. Defendant breached its duty of reasonable care and failed to exercise ordinary care in the marketing, promotion, and advertisement of the Rheos System to Plaintiff. Defendant was further negligent in failing to truthfully and timely disclose to Plaintiff that he would be responsible for all expenses to maintain the device if it did not receive FDA approval.

24. Plaintiff's physical injuries and damages are severe in nature, including but not limited to near certain death if the device is removed or is not properly maintained, mental anguish, and the expenses associated with replacing and maintaining the device.

25. Defendant was negligent, careless, reckless, grossly negligent, willful and wanton in the following particulars:

a. Failing to reasonably and truthfully promote, advertise, market, and inform Plaintiff about the device;

b. Promoting, advertising, marketing, and informing Plaintiff about the device while negligently and/or intentionally concealing and failing to disclose that Plaintiff would be responsible for the expenses of maintaining or replacing the device if it did not receive FDA approval; and

c. In such other and further particulars as may be ascertained during the course of discovery or trial of this case.

26. Plaintiff did not know that he would be wholly responsible for the costs to replace and maintain the device should it not receive FDA approval until less than 2 months from the date that Defendant informed Plaintiff that the device would need to be removed or maintained at his expense.

27. Defendant's negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiff has suffered and will continue to suffer into the future.

28. As a result of Defendant's acts and omissions described in this Complaint, Plaintiff was proximately caused to suffer and will continue to suffer actual damages, pecuniary loss, mental anguish, substantial medical costs and expenses to replace and maintain the device, and emotional injuries.

29. WHEREFORE, Plaintiff demands judgment in his favor and against the above named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT II

NEGLIGENT MISREPRESENTATION

30. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

31. Defendant had a duty to accurately and truthfully represent to the FDA, and U.S. consumers, including Plaintiff, the truth regarding the responsibility of patients to bear the costs of replacing and maintaining the Rheos System if the device did not receive FDA approval. Defendant informed Plaintiff numerous times, prior to and after the initial surgery, that it would bear the costs of replacing and maintaining the device even if it did not receive FDA approval. The misrepresentations made by Defendant, in fact, were false and known by Defendant to be false at the time the misrepresentations were made by Defendant.

32. Defendant failed to exercise ordinary care in making their representations concerning Plaintiff's responsibility to bear the costs to replace and maintain the device if it did not receive FDA approval.

33. Defendant negligently misrepresented that it would pay the costs for the device to be replaced and maintained even if the device did not receive FDA approval.

34. As a direct and proximate result of Defendant's acts and omissions described herein, Plaintiff has suffered serious emotional injuries, actual damages, pecuniary loss, mental anguish, and will incur substantial medical costs and expenses to replace and maintain the device.

35. WHEREFORE, Plaintiff demands judgment in his favor and against the above named Defendant, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT III

FRAUDULENT CONCEALMENT

36. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

37. Throughout the relevant time period, including prior to contacting Plaintiff as well as before and after the initial surgery, Defendant knew that Plaintiff would be responsible for any medical costs to replace and maintain the device if it did not receive FDA approval.

38. Defendant fraudulently concealed from or failed to disclose to Plaintiff that he would be responsible for all medical costs to replace and maintain the device if it did not receive FDA approval.

39. Defendant was under a duty to Plaintiff to disclose and warn of his responsibility to bear the costs to replace and maintain the device if it did not receive FDA approval because:

a. Defendant was in a superior position to know that Plaintiff would be responsible for costs to replace and maintain the device;

b. Defendant knowingly made false claims that it would pay for the costs to replace and maintain the device even if the device did not receive FDA approval; and

c. Defendant fraudulently and affirmatively concealed that it would not pay for the costs to replace and maintain the device if it did not receive FDA approval from Plaintiff.

40. The facts concealed or not disclosed by Defendant to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether to participate in the trial and in deciding how to prepare for future medical expenses associated with the replacement and maintenance of the device if it did not receive FDA approval.

41. Defendant intentionally concealed or failed to disclose that Plaintiff would be responsible for the costs to replace and maintain the device so that Plaintiff would participate in the clinical trial, as Defendant needed test subjects for the device. Plaintiff justifiably acted or relied upon, to his detriment, the concealed or non-disclosed facts.

42. As a result of Defendant's foregoing acts and omissions, Plaintiff was or still is caused to suffer severe and personal injuries, emotional injuries, actual damages, mental anguish, diminished enjoyment of life, impending death, and pecuniary loss for the medical costs associated with replacing and maintaining the device. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

43. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT IV

CONSTRUCTIVE FRAUD

44. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

45. Defendant was in a unique position of knowledge concerning the true costs to replace and maintain the device and the responsibility for such costs if the device did not receive FDA approval, which knowledge was not possessed by Plaintiff, and Defendant thereby held a position of superiority over Plaintiff.

46. Despite its unique knowledge regarding Plaintiff's responsibility to bear the costs to replace and maintain the device if it did not receive FDA approval, Defendant suppressed, concealed, omitted, or misrepresented this information to Plaintiff.

47. Defendant has concealed and suppressed material information regarding Plaintiff's responsibility to bear the costs to replace and maintain the device if it did not receive FDA approval. Instead, Defendant misrepresented on numerous occasions and over the course of several years that it would pay for the costs to maintain and replace the device even if it did not receive FDA approval.

48. On information and belief, Defendant's misrepresentations are or were designed to induce Plaintiff to participate in the clinical trial. Plaintiff relied upon Defendant's misrepresentations.

49. Defendant took unconscionable advantage of its dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendant's representations.

50. As a result of Defendant's foregoing acts and omissions, Plaintiff was or still is caused to suffer severe and personal injuries, emotional injuries, actual damages, mental anguish, diminished enjoyment of life, impending death, and pecuniary loss for the medical costs associated with replacing and maintaining the device. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

51. As a foreseeable, direct and proximate result of Defendant's willful and wanton misconduct and reckless disregard for Plaintiff's well-being, Plaintiff is entitled to punitive and exemplary damages as well as compensatory damages.

52. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT V

FRAUD

53. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

54. Defendant intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff that it would bear the costs of replacing and maintaining the device even if it did not receive FDA approval.

55. Defendant knew or should have known at the time it made its fraudulent misrepresentations, that its misrepresentations were false and fraudulent regarding Plaintiff's

responsibility to pay for the costs associated with the replacement and maintenance of the device should it not receive FDA approval. Defendant made its fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the Plaintiff.

56. Defendant's fraudulent misrepresentations were made with the intent of defrauding and deceiving the Plaintiff, and also inducing Plaintiff to participate in the clinical trial.

57. Defendant's intentional concealment and omissions of material fact concerning its intent to pay for the costs to replace and maintain the device if it did not receive FDA approval were made purposefully, willfully, wantonly, fraudulently, and with reckless disregard for the health and safety of Plaintiff, with reckless intent to mislead, to cause Plaintiff to participate in the clinical trial.

58. At the time Defendant made its misrepresentations, and at the time Plaintiff participated in the clinical trial, Plaintiff was unaware of the Defendant's falsehoods, and reasonably believed them to be true.

59. Defendant knew and had reason to know that Plaintiff would be solely responsible for the costs to replace or maintain the device if it did not receive FDA approval and that Plaintiff faced certain death without the device.

60. In reliance upon Defendant's false and fraudulent misrepresentations, Plaintiff was induced to, and did participate in the clinical trial. Defendant knew and had reason to know that Plaintiff did not have the ability to determine the true facts intentionally concealed by Defendant regarding costs associated with replacing and maintaining the device if it did not receive FDA approval.

61. Plaintiff reasonably relied upon Defendant's misrepresentations, where knowledge of the concealed facts was critical to understanding Plaintiff's participation in the trial and preparation for the costs associated with replacing and maintaining the device if it did not receive FDA approval.

62. As a result of Defendant's foregoing acts and omissions, Plaintiff was or still is caused to suffer severe and personal injuries, emotional injuries, actual damages, mental anguish, diminished enjoyment of life, impending death, and pecuniary loss for the medical costs associated with replacing and maintaining the device. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

63. As a foreseeable, direct and proximate result of Defendant's willful and wanton misconduct and reckless disregard for Plaintiff's well-being, Plaintiff is entitled to punitive and exemplary damages as well as compensatory damages.

64. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VI

VIOLATION OF SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT

65. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

66. Defendant's actions and/or omissions as described herein violate S.C. Code Ann. § 39-5-10, et seq., which pertains to unfair methods of completion and unfair or deceptive acts or practices, in that Defendant misrepresented to Plaintiff that it would pay for the costs to replace and maintain the device if it did not receive FDA approval. Defendant's actions were calculated to result in monetary gain for the Defendant at the expense of the Plaintiff. Plaintiff has suffered ascertainable loss as a result of Defendant's actions in violation of the Act, as set forth herein.

67. Unfair methods of competition and unfair or deceptive acts or practices are defined and declared unlawful in S.C. Code Ann. §39-5-10, et. seq.

68. Defendant violated the South Carolina Unfair Trade Practices Act by engaging in and proposing to engage in unfair trade practices by means of the following unlawful, unfair and fraudulent acts and practices:

a. Knowingly and intentionally representing that it would pay for the costs to replace and maintain the device even if it did not receive FDA approval.

b. Acting, using, or employing deception, fraud, false pretenses, false promises or misrepresentations, and/or concealed, suppressed or omitted material facts with the intent that participants of the clinical trial, including Plaintiff, rely upon such concealment, suppression, or omission, in connection with participating in the study.

69. The misrepresentations and omissions of Defendant described herein were likely to deceive, induce, and mislead the Plaintiff and Defendant knew or should have known that Plaintiff would be deceived, induced, and misled.

70. Defendant's actions and omissions as set forth herein evidence a lack of good faith, honesty in fact, and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of South Carolina Unfair Trade Practices Act.

71. As a proximate result of the acts of unfair and deceptive trade practices and/or consumer fraud set forth above, Plaintiff has been deceived, induced, and misled.

72. Defendant, its agents and/or employees acted willfully, knowingly, intentionally, unconscionably, illegally, unlawfully, and committed deceptive trade practices and/or consumer fraud.

73. As a result of the acts of the unfair and deceptive trade practices and/or consumer fraud described above, Plaintiff has suffered actual, ascertainable loss for which Defendant is liable. The unlawful trade practices engaged in by the Defendant has an adverse impact on the public interest by reason of established procedures being utilized thereby creating the potential repetition.

74. Plaintiff was injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at Plaintiff and study participants was to gather test subjects to participate in the clinical trial under the false impression that Defendant would pay for the costs to replace and maintain the device even if it did not receive FDA approval.

75. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and advertisement of the device.

76. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to trial participants, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes applicable to this action.

77. As a result of Defendant's foregoing acts and omissions, Plaintiff was or still is caused to suffer severe and personal injuries, emotional injuries, actual damages, mental anguish, diminished enjoyment of life, impending death, and pecuniary loss for the medical costs associated with replacing and maintaining the device. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

78. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VII

PROMISSORY ESTOPPEL

79. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

80. Defendant made promises and representations to Plaintiff that it would continue to bear the costs to replace and maintain the device even if it did not receive FDA approval in exchange for Plaintiff's participation in the clinical trial.

81. Defendant's representations to Plaintiff constituted unambiguous promises to Plaintiff to perform the actions specified therein.

82. Plaintiff reasonably relied on such promises by Defendant for several years and such reliance on the promises was expected and foreseeable by Defendant.

83. Plaintiff is informed and believes that Defendant should be estopped from denying the existence of the promises made by Defendant to Plaintiff and estopped from denying the enforceability of the aforesaid promises to Plaintiff.

84. As a result of Defendant's promises and representations, Plaintiff was or still is caused to suffer severe and personal injuries, emotional injuries, actual damages, mental anguish, diminished enjoyment of life, impending death, and pecuniary loss for the medical costs associated with replacing and maintaining the device. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

85. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT VIII

BREACH OF CONTRACT

86. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

87. Plaintiff and Defendant entered into a contract, supported by consideration, in which Defendant agreed to pay for the costs to replace and maintain the device regardless of FDA approval in exchange for Plaintiff's participation in the clinical trial.

88. Plaintiff participated in the clinical trial but Defendant has refused to pay for future costs to replace and maintain the device.

89. As a direct and proximate result of Defendant's breach of contract, Plaintiff has incurred and will continue to incur actual damages, pecuniary loss, consequential damages, and other injuries. As a direct and proximate result of Defendant's breach of contract, Plaintiff has required and will require healthcare and services, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care or hospital care and medical services.

90. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant, for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

COUNT IX

PUNITIVE DAMAGES

91. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

92. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendant's intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendant's reckless disregard for Plaintiff's safety and welfare. Defendant intentionally and fraudulently misrepresented facts and information to Plaintiff by making intentionally false and fraudulent misrepresentations. Defendant intentionally concealed the true facts and information regarding Plaintiff's responsibility to bear the costs of replacing and maintaining the device if it did not meet FDA approval

93. The aforementioned conduct of Defendant was committed with knowing, conscious, and deliberate disregard of the rights and safety of the Plaintiff, thereby entitling

Plaintiff to punitive damages in the amount appropriate to punish Defendant and deter it from similar conduct in the future.

94. WHEREFORE, Plaintiff demands judgment in his favor and against the above-named Defendant for damages in an amount in excess of the jurisdictional limits of this Court, together with all lawful fees, costs and such other relief as this Court deems just and proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff demands judgment against Defendant as follows:

A. Awarding Plaintiff compensatory damages against Defendant in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

B. Awarding Plaintiff treble damages against Defendant so to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;

C. Awarding Plaintiff punitive damages against Defendants in an amount sufficient to punish Defendant for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding Plaintiff costs and disbursements, costs of investigation, attorneys' fees and all other relief available under applicable law;

E. Awarding that the costs of this action be taxed to Defendant;

F. Awarding injunctive relief such that Defendant would be required to continue to replace and maintain the device as required and bear the associated costs; and

G. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

The Plaintiff demands trial by jury on all of the triable issues of this Complaint.

Respectfully Submitted,

MIKE KELLY LAW GROUP, LLC

BY: /s/ D. Michael Kelly_____
D. Michael Kelly
Fed. Id. No. 2299
mkelly@mklawgroup.com
Brad D. Hewett
Fed. Id. No. 10388
bhewett@mklawgroup.com
Walton J. McLeod, IV
Fed. Id. No. 10549
500 Taylor Street
P.O. Box 8113
Columbia, SC 29202
803/726-0123 (p)
803/252-7145 (f)
Attorneys for Plaintiff

Dated: May 21, 2015